UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,934	07/08/2003	Rafael Herrmann	BB1102 US DIV	9192

23906 7590 07/06/2005

E I DU PONT DE NEMOURS AND COMPANY
LEGAL PATENT RECORDS CENTER
BARLEY MILL PLAZA 25/1128
4417 LANCASTER PIKE
WILMINGTON, DE 19805

EXAMINER	
BUGAISKY, GABRIELE E	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,934	HERRMANN ET AL.	
	Examiner	Art Unit	
	Gabriele E. BUGAISKY	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, Claims 1-10 and 16-17 and 16-17 drawn to an isolated polynucleotide encoding a scorpion toxin of SEQ ID NO:2, host cells and virion constructs containing the polynucleotide, classified in class 435, subclass 325.

Group II, Claims 1-10 and 16-17, drawn to an isolated polynucleotide encoding a scorpion toxin of SEQ ID NO:4, host cells and virion constructs containing the polynucleotide, classified in class 435, subclass 325 .

Group III, Claims 1-10 and 16-17, drawn to an isolated polynucleotide encoding a scorpion toxin of SEQ ID NO:6, host cells and virion constructs containing the polynucleotide, classified in class 435, subclass 325.

Group IV, Claims 1-10 and 16-17, drawn to an isolated polynucleotide encoding a scorpion toxin of SEQ ID NO:8, host cells and virion constructs containing the polynucleotide, and a method for transforming a cell , classified in class 435, subclass 325.

Group V, Claims 1-10 and 16-17, drawn to an isolated polynucleotide encoding a scorpion toxin of SEQ ID NO:10, host cells and virion constructs containing the polynucleotide, classified in class 435, subclass 325.

Group VI, Claims 1-10 and 16-17, drawn to an isolated polynucleotide encoding a scorpion toxin of SEQ ID NO:12, host cells and virion constructs containing the polynucleotide, classified in class 435, subclass 325

Group VII, Claims 1-10 and 16-17, drawn to an isolated polynucleotide encoding a scorpion toxin of SEQ ID NO:14, host cells and virion constructs containing the polynucleotide, classified in class 435, subclass 325.

Group VIII, Claims 1-10 and 16-17, drawn to an isolated polynucleotide encoding a scorpion toxin of SEQ ID NO:16, host cells and virion constructs containing the polynucleotide, classified in class 435, subclass 325.

Group IX, Claim 11, drawn to a scorpion toxin of SEQ ID NO:2, classified in class 530, subclass 324.

Group X, Claim 11, drawn to a scorpion toxin of SEQ ID NO:4, classified in class 530, subclass 324.

Group XI, Claim 11, drawn to a scorpion toxin of SEQ ID NO:6, classified in class 530, subclass 324.

Group XII, Claim 11, drawn to a scorpion toxin of SEQ ID NO:8, classified in class 530, subclass 324.

Group XIII, Claim 11, drawn to a scorpion toxin of SEQ ID NO:10, classified in class 530, subclass 324.

Group XIV, Claim 11, drawn to a scorpion toxin of SEQ ID NO:12, classified in class 530, subclass 324.

Group XV, Claim 11, drawn to a scorpion toxin of SEQ ID NO:14, classified in class 530, subclass 324.

Group XVI, Claim 11, drawn to a scorpion toxin of SEQ ID NO:16, classified in class 530, subclass 324.

Group XVII. Claims 12-14, drawn to a method of selecting a polynucleotide by measuring the amount of polypeptide of SEQ ID NO:2 produced by a transformed cell, classified in class 436, subclass 86.

Group XVIII. Claims 12-14, drawn to a method of selecting a polynucleotide by measuring the amount of polypeptide of SEQ ID NO:4 produced by a transformed cell, classified in class 436, subclass 86.

Group XIX. Claims 12-14, drawn to a method of selecting a polynucleotide by measuring the amount of polypeptide of SEQ ID NO:6 produced by a transformed cell, classified in class 436, subclass 86.

Group XX. Claims 12-14, drawn to a method of selecting a polynucleotide by measuring the amount of polypeptide of SEQ ID NO:8 produced by a transformed cell, classified in class 436, subclass 86.

Group XXI. Claims 12-14, drawn to a method of selecting a polynucleotide by measuring the amount of polypeptide of SEQ ID NO:10 produced by a transformed cell, classified in class 436, subclass 86.

Group XXII. Claims 12-14, drawn to a method of selecting a polynucleotide by measuring the amount of polypeptide of SEQ ID NO:12 produced by a transformed cell, classified in class 436, subclass 86.

Group XXIII. Claims 12-14, drawn to a method of selecting a polynucleotide by measuring the amount of polypeptide of SEQ ID NO:14 produced by a transformed cell, classified in class 436, subclass 86.

Group XXIV. Claims 12-14, drawn to a method of selecting a polynucleotide by measuring the amount of polypeptide of SEQ ID NO:16 produced by a transformed cell, classified in class 436, subclass 86.

Group XXV. Claim 15, drawn to a method of obtaining a polynucleotide encoding a scorpion toxin by hybridization with the complement of a polynucleotide fragment encoding a portion of SEQ ID NO:2, classified in class 435, subclass 6.

Group XXVI. Claim 15, drawn to a method of obtaining a polynucleotide encoding a scorpion toxin by hybridization with the complement of a polynucleotide fragment encoding a portion of SEQ ID NO:4, classified in class 435, subclass 6.

Group XXVII. Claim 15, drawn to a method of obtaining a polynucleotide encoding a scorpion toxin by hybridization with the complement of a polynucleotide fragment encoding a portion of SEQ ID NO:6, classified in class 435, subclass 6.

Group XXVIII. Claim 15, drawn to a method of obtaining a polynucleotide encoding a scorpion toxin by hybridization with the complement of a polynucleotide fragment encoding a portion of SEQ ID NO:8, classified in class 435, subclass 6.

Group XXIX. Claim 15, drawn to a method of obtaining a polynucleotide encoding a scorpion toxin by hybridization with the complement of a polynucleotide fragment encoding a portion of SEQ ID NO:10, classified in class 435, subclass 6.

Group XXX. Claim 15, drawn to a method of obtaining a polynucleotide encoding a scorpion toxin by hybridization with the complement of a polynucleotide fragment encoding a portion of SEQ ID NO:12, classified in class 435, subclass 6.

Group XXXI. Claim 15, drawn to a method of obtaining a polynucleotide encoding a scorpion toxin by hybridization with the complement of a polynucleotide fragment encoding a portion of SEQ ID NO:14, classified in class 435, subclass 6.

Group XXXII. Claim 15, drawn to a method of obtaining a polynucleotide encoding a scorpion toxin by hybridization with the complement of a polynucleotide fragment encoding a portion of SEQ ID NO:16, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII are unrelated proteins with different primary and tertiary structures. SEQ ID NO:2, for example is, 57 amino acids with 4 disulfide bridges and has a cysteine backbone of $X_{13}CX_4CX_9CX_5CX_3CX_{10}CX_4CXCX$, SEQ ID NO:4 is 39 amino acids with 3 disulfide bridges and a cysteine backbone of $X_9CX_3CX_3CX_9CX_4CXCX_4$, SEQ I DNO:6 is 29 amino acids with 3 disulfide bridges and a cysteine backbone of $X_2CX_2CX_3CX_8CX_4CXCX_3$ etc. Clearly, these proteins do not share a common structure.

Inventions I-VIII and IX-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. A function of a polynucleotide is to encode protein, whereas the protein itself serves as a toxin.

Inventions I-VIII and XVII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. There is no disclosure that a purified toxin has any use in a method of using a recombinant DNA.

Inventions IX-XVI and XVII-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA can be used in 2 different claimed methods of screening-by hybridization *in vitro* or by expression in transformed cells. Further, the DNA can be used to generate large amounts of protein from transformed cells.

Inventions IX-XVI encode unrelated proteins with different primary and tertiary structures, and thus are unrelated DNA sequences.

Inventions XVII-XXIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods of use of different products.

Inventions XVII-XXIV and XXV-XXXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are have different modes of operation. One set requires screening by expression in transformed cells, whereas the other requires hybridization in vitro. Each set of methods requires different steps..

Inventions XV-XXXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods of use of different products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (571) 272-0945. The examiner can normally be reached on Tues.- Fri 8:15 AM-1:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-283-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1656

01 July 2005